DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Re: Plendil
Docket No. 91E-0377

DEC 12 1991

#19

The Honorable Harry F. Manbeck, Jr.
Assistant Secretary of Commerce
and Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Commissioner Manbeck:

This is in regard to the application for patent term extension for U.S. Patent No. 4,264,611, filed by Aktiebolaget Astra, under 35 U.S.C. 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Plendil, the human drug product claimed by the patent.

The total length of the review period for Plendil is 2,494 days. Of this time, 1,248 days occurred during the testing phase and 1,246 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: September 27, 1984.

   The applicant claims January 16, 1986, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was September 27, 1984, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under subsection 505(b) of the Federal Food, Drug, and Cosmetic Act: February 26, 1988.

   FDA has verified the applicant's claim that NDA 19-834 was filed on February 26, 1988.

3. The date the application was approved: July 25, 1991.

FDA has verified the applicant's claim that NDA 19-834 was approved on July 25, 1991. This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Edward V. Filardi, Esq.
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